AMENDMENTS TO THE CLAIMS

Claims 1-6 are pending.

Claims 1-6 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner argues, for example, that the disclosure of 0.5-30% or 1-25% of at least one active ingredient does not support a claim limitation of 0.5 to 25% of at least one active ingredient. To the contrary, applicants urge that such disclosure does provide adequate support for such a claim limitation. In an analogous situation in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), cited in MPEP 2163.05(III), the court found that a description in the specification of a range of "25% to 60%" and examples of "36%" and "50%" was sufficient to support a claimed range of "between 35% and 60%." Thus, from *Wertheim*, it can be concluded that a disclosed range is sufficient to support independently the lower and upper limits of that range. Therefore, the lower limit of the presently claimed range of the at least one active ingredient finds support in the disclosure of 0.5-30% and the upper limit finds support in the disclosure of 1-25%. The same holds true for the cyclodextrin and the polymeric binder.

The recitation of "dialkyl sulfates" finds support at page 7, lines 42-43. The recitation of "carbonyl chlorides" finds support at page 8, lines 8-9.

Claims 1-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baert et al. (US 6,365,188) in view of Stella et al. (US 6,046,177) in further view of Murata et al. (US 5,500,221). Applicants respectfully traverse this rejection.

The object of the present invention is to provide a process for producing solid dosage forms with faster release of active ingredient (see page 2, lines 33 to 35).

The Stella reference teaches that binders such as polyvinyl pyrrolidone or polyethylene glycol may optionally be used in the pharmaceutical formulation described therein. It further mentions that some of the listed binders can also be considered as release rate modifiers, which are a mandatory component of the Stella composition. However, Stella does not teach which of the listed binders are suitable as release rate modifiers. Moreover, this document does not specify what effect can be attributed to the respective binders or release rate modifiers, namely whether they provide for a delayed, targeted, sustained etc. dosage form. In example 10 of this prior art document (col. 45) (viewed as closest to the process of the present invention), a granulation is prepared by blending an active ingredient, SBE-cyclodextrin, polyethylene glycol 6000, hydroxypropyl methylcellulose and citric acid and submitting the mixture to a hot melt extrusion. The thus obtained granules are then prepared to give tablets which are submitted to a dissolution test. The dissolution test shows that the active ingredient is released slowly in a dissolution medium or into the gastrointestinal tract (see col. 45, lines 29/30). Therefore, having the object to provide a process for producing solid dosage forms with a fast release of the active ingredient, a skilled person would not have had the slightest motivation to use the binder of Stella in the process of Baert since he would have deduced from example 10 that this type of binders leads to a delayed or sustained release of the active ingredient and in any case not to the desired fast release. In other words, the present invention exhibits unexpected results.

What is more, a person skilled in the art would not have been motivated to combine the teaching of the two documents in such a way that the cyclodextrins described in Baert et al. are used in the process instead of the specific cyclodextrin of Stella: From the whole content of Stella a skilled person would deduce that it is indispensable to use the sulfoalkylether cyclodextrins specified therein in order to avoid problems and disadvantages connected with

mixtures of different cyclodextrins and active ingredients, such as low solubility or bioavailability. For instance, example 11 describes the preparation of a solid drug form containing testosterone and SBE-13-cyclodextrin or, for comparison, hydroxypropyl-β-cyclodextrin. As can be seen from figure 25, the drug form containing SBE-β-cyclodextrin releases a greater amount of testosterone at a more acceptable rate than the drug form containing the "standard" hydroxypropyl-β-cyclodextrin (see also col. 20, line 58 to cot 21, line 4 of the Stella reference).

Hence, a person skilled in the art would have deduced from the Stella document that

1. it is disadvantageous to replace the specific sulfoalkylether cyclodextrin by a standard cyclodextrin and, what is more,

2. that a polymeric binder leads to a drug form with a slower release rate.

Similar arguments apply to the combination of Baert et al. with Stella et al. and Murata et al.: Murata describes a sustained-release suppository preparation which shall exhibit no rapid increase in blood concentration immediately after the administration of the drug. Accordingly, a person skilled in the art would have deduced that the polymers which are used for adjusting the release rate of the drug, such as polyvinylpyrrolidone, provide for a slower release of the active ingredient.

Claims 1-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/58529 to Meerpoel et al. in view of Klimesch et al. (US 4,880,585). Applicants note that the publication date of Meerpoel et al. is November 18, 1999, while the priority date of the present application is March 12, 1999. Accordingly, Meerpoel et al. is not prior art with respect to the present application. Applicants are currently preparing a verified translation of said priority document and will file it as soon as available.